

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
No. 3:22-CV-0191-MOC-DCK

KANAUTICA ZAYRE-BROWN,)	
)	
Plaintiff,)	
)	
v.)	EXPERT REPORT OF JOSEPH V.
)	PENN, MD, CCHP-MH, LFAPA
THE NORTH CAROLINA DEPARTMENT)	
OF ADULT CORRECTION, et al.,)	
)	
Defendants.)	

I. Introduction and Expert Background

I was retained in this matter by Defendants based on my expertise in the provision of psychiatric, mental health, and certain other medical and health care services across correctional settings. I was asked to provide opinions and conclusions regarding the adequacy and appropriateness of policies and procedures used by the Department for evaluating and managing requests for accommodations by transgender patients. Additionally, I was asked to offer opinions and conclusions about the Department’s formulation and application of the phrase “medical necessity” within state prisons. I was also asked to offer opinions and conclusions regarding Defendants’ evaluation of Plaintiff’s request for a vulvoplasty as a surgical intervention to treat her gender dysphoria.

A. Summary Statement of Qualifications

I am a correctional and forensic psychiatrist based in Conroe, Texas. I am a licensed physician triple board-certified in forensic psychiatry, general psychiatry, and child and adolescent psychiatry, and a Clinical Professor in the Department of Psychiatry and Behavioral Sciences at the University of Texas Medical Branch (UTMB), Galveston, Texas. Over the past 30 years, I have

devoted most of my professional time to the practice, teaching, and clinical research within general adult, child and adolescent, forensic, and correctional psychiatry. Since 1999, I have focused my clinical, administrative, and forensic work primarily within correctional settings.

I achieved and have maintained a specialized certification as a Certified Correctional Health Professional-Mental Health (CCHP-MH) since 2004, which is provided by the National Commission on Correctional Health Care (“NCCHC”). I am a NCCHC physician surveyor, serve on the NCCHC Accreditation and Standards Committee, and on the NCCHC board, representing the American Academy of Psychiatry and the Law (“AAPL”). I have also provided specialized technical assistance, trainings, and consultation to juvenile facilities, jails, and prisons nationally, internationally, and the US territory, Puerto Rico, most recently.

I am the Director of Mental Health Services of the UTMB Correctional Managed Care (CMC), a university-based correctional health care system. UTMB CMC provides direct medical, dental, nursing, psychiatric, mental health, gender dysphoria and other specialty care to state prisoners in the Texas Department of Criminal Justice (“TDCJ”), which is the largest state prison system in the country. In this position, I am responsible for, provide, and oversee the psychiatric, psychological, and mental health services at eighty state jail and state prison units throughout Texas. I have held this position since February 2008.

As a practicing correctional psychiatric physician, I evaluate, diagnose, treat, and oversee the provision of mental health services for incarcerated individuals with mental disorders and behavioral issues. Similarly, I evaluate, diagnose, and treat patients with gender dysphoria evaluation, and supervise other clinicians that do the same. Additionally, I directly oversee the statewide clinical evaluation and treatment program for TDCJ patients who seek treatment for gender dysphoria. I also provide consultation on particularly complicated patients.

I have developed and maintain clinical knowledge regarding the mental health and health care needs of incarcerated transgender and gender diverse individuals. As such, I am familiar with the *Standards of Care for the Health of Transgender and Gender Diverse People, WPATH 8* (“WPATH 8”) and the prior Version 7, published by the World Professional Association of Transgender Health (“WPATH”). I am also generally familiar with other scientific and peer-reviewed literature relevant to the provision of health care to this patient population both in community and in correctional settings.

I am the Chair of the Joint Mental Health Work Group, and the Co-Chair of the Joint Gender Dysphoria Work Group. In this capacity I oversee the review and revision of all policies, procedures, clinical practices, disease management guidelines, formulary and non-formulary psychotropic and gender affirming medications for incarcerated TDCJ patients. Also, I have experience developing and implementing policies concerning the care and management of the incarcerated transgender and gender diverse population. More specifically, I oversaw the systemwide development, revisions, and implementation of a disease management guideline for the evaluation and treatment of incarcerated adults seeking evaluation and treatment for gender dysphoria.

I also provided input and assisted with revisions to the State of Texas’s Correctional Managed Health Care Committee policy entitled Policy G-51.11 of the Correctional Managed Health Care Policy Manual, which concerns the treatment of incarcerated persons with intersex conditions and gender dysphoria. And, I assisted in revising and approving, the NCCHC’s 2020 position statement entitled: *Transgender and Gender Diverse Health Care in Correctional Settings*.¹

¹ <https://www.ncchc.org/transgender-and-gender-diverse-health-care-in-correctional-settings-2020>

Additionally, I oversaw the development, implementation, and expansion of a statewide specialized gender dysphoria referral and clinical program, a joint operation of the UTMB CMC, the TDCJ, and Texas Tech University. This program is used throughout the TDCJ system statewide. This program uses telemedicine to provide specialty clinics across the jurisdiction to undergo evaluation, diagnosis, treatment, and subsequent follow-up. Based on patient experience and feedback, and from health care, and custody staff's perspectives, the program has been a tremendous success. As a result of the program's success, we have received numerous external requests for lectures/presentations describing this novel program at several NCCHC and American Correctional Association annual meetings and other health care conferences, and other venues. I continue to oversee and maintain direct clinical involvement in this program.

I also have direct clinical and supervisory experience working with this patient population. I have personally evaluated, diagnosed, performed chart reviews, ordered or re-ordered gender affirming hormone medications, reviewed lab studies, performed second opinions, and consulted with other health care staff, including, endocrinologists, internal medicine physicians, family physicians, psychiatrists, and others. In total, I estimate that I have treated more than 1,500 incarcerated transgender patients with or without gender dysphoria. I also directly oversee mental health care providers in the UTMB CMC system who provide evaluation, diagnosis, and direct patient care to transgender patients. Additionally, I provide other consultation and behavioral treatment recommendations regarding this patient population to psychiatric and mental health, nursing, and medical staff and to TDCJ custody and health services leadership.

To gain additional direct patient care experience with this patient population, I completed a specialized clinical training program regarding the evaluation and treatment of this patient population. I completed this training between December 2014 and December 2016 with Dr. Walter

Meyer, Professor Emeritus, and now retired UTMB faculty psychiatrist and endocrinologist. Dr. Meyer is a respected international leader in transgender health care. For this training program, I would routinely travel to the UTMB CMC Hospital specialty clinics in Galveston, Texas, to train under the direct supervision of Dr. Walter Meyer. Much of this training consisted of additional readings, patient chart reviews, clinical supervision, and case discussion meetings with Dr. Meyer. During these discussions, Dr. Meyer and I would review relevant guidelines, and patient evaluations and treatment plans. I completed this additional specialized clinical training program to improve my diagnostic skills and competence in evaluating and managing this patient population and to attempt to optimize our health care delivery to this group. Subsequent to 2016, I continued my ongoing clinical collaboration and case discussion with Dr. Meyer up through his retirement a few years ago.

In addition to evaluating, diagnosing, treating, and consulting on patients in the TDCJ system, I have performed second opinion evaluations/consultations in other states. I have also served as a consultant to several state prison systems including Colorado, Kansas, New Jersey, and California regarding gender dysphoria diagnoses, evaluation and treatment programs, policies, and practices, and medical and surgical interventions for various state inmates. I have presented nationally and internationally regarding the evaluation and diagnosis, clinical management, and treatment of transgender and gender diverse individuals within correctional settings.

Due to my 30 years of direct patient care and administrative work and particular career focus within correctional settings, I maintain additional knowledge regarding the range of clinical, professional, ethical, legal, patient safety, and other correctional specific issues such as PREA (Prison Rape Elimination Act), health care and custody staffing and supervision, access to and continuity of health care, and organizational challenges to those who evaluate and treat

incarcerated transgender individuals with or without gender dysphoria. I also maintain necessary familiarity with custody and classification issues such as unit, program, and housing assignments, basic unit operations, disciplinary infractions, custody status, unit custody classification hearings, restrictive housing, custody supervision, custody classification issues such as age, gender, height, weight, and security threat group (gang affiliations), protective custody status, life endangerment claims, and the like.

For a more detailed statement of my education, training, and experience, see paragraphs 1 through 20 of my affidavit (DE-18-8), and my CV (DE-18-9) both of which have previously been filed in this case, and which I fully incorporate herein by reference.

B. Information Considered in Forming Opinions

In forming the conclusions and opinions set out in this report, I reviewed and considered a variety of materials and information, which are set forth in Appendix A. Generally speaking, these materials and information include various medical and health care records, and other records and documents maintained by the North Carolina Department of Adult Correction (“the Department”) concerning Plaintiff, Mrs. Zayre-Brown, that were produced in discovery in this matter. I have also reviewed several legal filings in this matter, including those related to Plaintiff’s motion for a preliminary injunction and Defendants’ motion to dismiss.

Additionally, I have reviewed the report of Randi C. Ettner, Ph.D., Plaintiff’s expert, dated February 2, 2023, and her previous declarations. I also reviewed WPATH 8 and its predecessor, version 7. And I have watched the January 28, 2023, video-taped deposition of Plaintiff and reviewed the transcript of the same.

I have reviewed the Department’s policy, titled *Evaluation and Management of Transgender Offenders* (“Policy”). And I have reviewed the deposition transcripts of the

Department's 30(b)(6) deposition, as well as the transcripts of the depositions of Lewis Jonathan Peiper, Ph.D., Arthur Leslie Campbell, III, M.D., Brian Sheitman, M.D., Gary Junker, Ph.D., and Patricia Hahn, Ph.D.

Furthermore, I reviewed the expert reports of Fan Li, Ph.D., and Sara E. Boyd, Ph.D, including a recording of Dr. Boyd's June 20, 2023, in-person assessment of Mrs. Zayre-Brown.

C. Compensation, Other Expert Testimony, and List of Publications

For my work on this case, I am charging \$500.00 per hour for all services that I render, except for time spent providing deposition or in-court testimony, for which I charge \$750.00 per hour. A list of all other cases, during the previous 4 years, in which I have testified as an expert at trial or by deposition is attached as Appendix B. Lastly, a list of my publications can be found on pages 9 – 13 of my CV (DE-18-9).

II. Discussion

In this report, I discuss my conclusions and opinions, which can be aggregated into the following three categories. First, I address the Department's policies and processes for making determinations regarding the provision of medical care for transgender patients. Second, I discuss the formulation and application of the phrase "medical necessity" based on my education, training, and experience in the correctional health care context. Finally, I review the Department's decision to not approve Plaintiff's request for a vulvoplasty as treatment for gender dysphoria.

A. Summary of Opinions

Policy and Procedure. The Department's policy, *Evaluation and Management of Transgender Offenders* ("the Policy" or "the EMTO policy") sets out a framework for addressing requests for accommodations that may be made by transgender and gender diverse individuals in the correctional setting. Because these accommodations requests can and do include non-medical

requests (*e.g.*, housing assignments, clothing, and certain canteen items, etc.), medical requests (*e.g.*, gender affirming hormone therapy, medications, and surgical interventions), or both, it is essential that these requests be reviewed by a multidisciplinary panel. A multidisciplinary approach to reviewing such requests is common within correctional systems. Based on my education, training, and experience in correctional healthcare, the Department's policy is well designed and meets or exceeds what I would consider to be a reasonably adequate policy for addressing the myriad of requests for accommodations which can be made by the transgender and gender diverse population in the carceral setting.

Medical Necessity. There is no precise or singular definition of the phrase “medical necessity.” A reasonable understanding of the phrase, however, can include a patient specific risk-benefit analysis and a determination of whether the proposed treatment is supported by rigorous scientific evidence. This determination involves two steps. First, the risk-benefit analysis examines whether the procedure is one which is necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. The second step involves assessing the efficacy of the intervention at issue demonstrated by rigorous scientific study. The formulation of “medical necessity” that Dr. Ettner advances does not involve either step. Instead, Dr. Ettner’s “medical necessity” determination appears to turn on whether the contemplated intervention could provide some potential therapeutic benefit to the patient. Based upon my education, training, and experience in correctional healthcare, the formulation of “medical necessity” advanced by Dr. Ettner, a non-physician, community-based psychologist, who does not work within correctional settings, is unworkable and does not comport with a reasonable formulation of the phrase.

Review of Mrs. Zayre-Brown’s Request. The Department, through the Division Transgender Accommodation Review Committee (“Division TARC”), concluded that the

requested vulvoplasty was not medically necessary to treat Mrs. Zayre-Brown's gender dysphoria. Based on my review of the materials referenced earlier in this report, the Division TARC's decision appears to be based on two points.

First, the Division TARC concluded, after reviewing medical, mental health records, and considering the recommendations by outside consulting providers, that there was no clinical indication that the requested surgical procedure was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain.

Second, based primarily on the presentation of information by Arthur L. Campbell, III, M.D., the Department's Medical Director, the Division TARC concluded that there is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria.

The Division TARC's overall conclusion is consistent with my own ongoing review of the published evidence based empirical research on the topic. Additionally, this conclusion is supported by the report of Fan Li, Ph.D., from Duke University, who systematically analyzed more than 80 studies. It is my professional opinion, to a reasonable degree of medical/scientific certainty, based on my education, training, and experience, that given the lack of any ability to identify and quantify any baseline and outcomes of significant clinical markers of extreme and sustained distress identified by the Division TARC, and the absence of high-quality research on the efficacy of surgery as a treatment of gender dysphoria, and moreover the absolute lack of any published controlled studies or literature within any US correctional system to date, that the Division TARC's conclusion that the requested vulvoplasty was not medically necessary to treat Mrs. Zayre-Brown's gender dysphoria was a reasonable, appropriate, and well-supported evidence based health care decision.

B. The Department's Policy is Reasonable and Sound

Based on my decades of correctional health care experience, and my knowledge and training concerning the management of transgender patients with gender dysphoria in the carceral setting, it is my opinion that the Department's Policy comports with or exceeds what I would consider to be an acceptable standard for a comprehensive set of correctional healthcare protocols for the evaluation and management of such patients. Indeed, the Department's Policy and procedures are equivalent to those of other state prison systems, including some of the larger systems in the country.

For example, similar to other jurisdictions, the review of requests for accommodations in North Carolina includes input from multiple disciplines. Similarly, North Carolina, as in other states, uses a tiered review system where some requests are reviewed at the facility level review and others are either appealed to or reviewed at a higher level. In short, although there is some minor variability, in my professional opinion, the gender dysphoria review process utilized by North Carolina Department of Corrections falls well within accepted state prison correctional health care policies, procedures, and best practices.

1. Overview of the Policy and Review Process

The Department's Policy sets out a tiered review process for evaluating requests for accommodations made by transgender or gender diverse patients. The first tier of review is the Facility Transgender Accommodation Review Committee ("Facility TARC"). The Policy requires each prison facility to establish a Facility Transgender Accommodation Review Committee ("Facility TARC") that is tasked with reviewing "routine requests" for accommodations by transgender individuals. (DAC 3422-3425) The Policy defines "routine requests" as requests for

the continuation of hormone therapy, specific types of undergarments, particular cosmetic and other products, private showering, and intra-facility housing assignments. (DAC 3426)

The Department's review process as articulated in the Policy relies on input from multiple clinical and non-clinical disciplines. Each Facility TARC must include representatives from psychiatry (as needed), behavioral health, primary care, nursing, facility administration, unit management, and the facility Prison Rape Elimination Act (PREA) Compliance Manager. (DAC 3422)

Additionally, the Policy sets out basic parameters for how each review is to be conducted. The Facility TARC must be chaired by a psychologist or other health services representative. (DAC 3422) In the lead up to a review by the Facility TARC, synopses of any related medical examinations, any PREA related allegations and infractions history by the PREA compliance manager, any related behavioral health and psychiatric evaluations must be prepared in advance by the respective representative on the committee. (DAC 3425) For all reviews by the Facility TARC, the Policy sets out specific information which should be documented and summarized across disciplines. (DAC 3427-3428)

The Policy also permits an individual to appeal a decision by the Facility TARC for review by the Division TARC. (DAC 3423) The Facility TARC can also refer a request that falls outside these routine categories to the Division TARC. (DAC 3426) The Policy defines "non-routine requests" to include initiation of hormone therapy, gender-consistent facility assignment, and gender-affirming surgical requests—these requests are reviewed by the Division TARC. (DAC 3426-3427) The Policy also specifies which disciplines are required on the Division TARC by identifying specific positions to make up the committee. The Division TARC must, at a minimum,

be comprised of the Medical Director, the Chief of Psychiatry, the Behavioral Health Director, the Director of Rehabilitative Services and the PREA Director. (DAC 3422)

Additionally, the Policy also sets out a basic framework for each review. The Division TARC review shall include summary information regarding any psychological evaluation, relevant medical examination, prior medical and mental health records, and recent infraction history and PREA allegations, if any. (DAC 3427) For all reviews by the Division TARC the policy sets out specific information which should be documented and summarized across disciplines. (DAC 3427-3428) The Policy also requires that the Division TARC consider each request on a case-by-case basis. (DAC 3427) With respect to requests regarding surgical intervention or gender-identity consistent facility transfers, the recommendation of the Division TARC is referred to the Assistant Commissioner of Prisons and the Director of Health & Wellness Services for a final review and determination.² (DAC 3427)

In practice, the Division TARC meetings are co-chaired by the Department's Medical Director and the Behavioral Health Director. The Division TARC reaches a decision on a request by consensus and does so after discussion and consideration amongst the group. At these Division TARC meetings, the members of the group provide any relevant input from their respective disciplines.

In cases where clinical care is implicated by a request (*e.g.*, requests involving hormone therapy or surgical interventions) the Division TARC's discussion would largely be driven by input from the clinical members on the committee and not custody staff. In such instances, the Medical Director would present information based on a review of the patient's relevant medical

² It is my understanding that the position titles of the two individuals who conduct this final review have now changed with the restructure and move of prison operations out of the Department of Public Safety and over to the Department of Adult Correction.

history, including possible medical issues and comorbidities, chronic diseases, and other relevant health care conditions and, if necessary, discussion of research or other additional information to aid in the group's determination. Similarly, the Behavioral Health Director would provide information to the group based on a review of the patient's relevant mental and behavioral health records, including reference to any specific concerns indicated by the review. Likewise, the Chief of Psychiatry would provide input to the group based on a review of the patient's relevant psychiatric history, if any, and their mental health records, which would include any concerns of the potential risk to the same. The Division TARC would then discuss the case and arrive at a consensus decision. The non-clinical personnel on the committee may, depending on the factors of the case, provide relevant information to the committee as necessary.

Conversely, where the request at issue does not implicate clinical care, such as transfer requests, the non-clinical/custody-oriented members of the Division TARC would typically drive the discussion each providing input relative to their area of focus (*e.g.*, security, operations, programming, PREA). When reviewing a non-clinical request, the clinical personnel might provide information as needed and to the extent it may aid the committee in reaching a decision with respect to the non-clinical request at issue. However, the clinical personnel would largely defer to the custody-oriented personnel in such instances. And in cases that involve both clinical and non-clinical requests, the members of the committee would provide input from their respective focus areas each affording deference to other member's areas of focus.

2. Implications of the Policy and the Process

Several aspects of the Department's Policy and process contribute to its quality and effectiveness. First, the Department's multidisciplinary approach is critical to its comprehensiveness and efficiency. Because requests for accommodations by transgender or

gender diverse patients in the correctional setting may implicate clinical and non-clinical considerations, or both, it is essential to ensure that professionals from various disciplines are included in the decision-making process. As an example, when a transgender female requests a transfer to a female facility, the safety of and impact on both the requesting inmate and those already housed at the facility must be considered. A committee of decisionmakers without any experience in non-clinical areas, such as custody, security, programming, and operations would be ill-suited to adequately consider such a request alone.

Additionally, because the correctional environment is so interconnected, close coordination between custody, medical, and other staff is a must. For that reason, even when a request is clinical in nature, having non-clinical expertise present during those considerations is advisable as this provides the non-clinical side with the situational awareness necessary to execute its core functions in light of the Division TARC's decision. Even within the clinical sphere, the Policy requires input from multiple clinical disciplines, namely, medical, nursing, psychiatric, and behavioral health. Ultimately, the inclusion of clinical and non-clinical personnel on the Division TARC enables it to reach those decisions based on all relevant and necessary input from across the agency.

Another significant feature, and a best correctional health care practice, of the Department Policy is that it requires a case-by-case review and evaluation of various requests for interventions. Gender dysphoria falls along a spectrum and presents differently from patient to patient. There is also a myriad of other reasons for which a transgender patient might seek one or more various requests. For that reason, there is no singular solution or approach that can be applied in all situations. Accordingly, the type of intervention required to adequately address a patient's medical and/or behavioral health needs will likewise vary significantly from person to person. Thus, a

policy that requires that each request for an accommodation is evaluated based on patient-specific circumstances is a highly appropriate and reasonable approach. The type of case-by-case approach provided for in the Policy is one that is endorsed in the NCCHC's Position Statement cited above. Additionally, WPATH 8 broadly endorses an individualized approach when considering various treatment options.

Third, the layered decision-making approach (*i.e.*, the Facility and Division TARC and the final review) has many benefits. And each level of the process has an important function. Requiring the Facility TARC to initiate all requests permits those who interact with and are most familiar with the patient, and their needs, the ability to gather information and provide input. Additionally, starting all requests with a Facility TARC ensures that facility-level providers and custody personnel are aware of the request—this is important since they would be charged with facilitating the ultimate decision. This frontline input is thus valuable even with requests that the Facility TARC does not have the authority to decide. Furthermore, by authorizing the Facility TARC to make certain decisions, the Department can efficiently process requests and ensure that higher level review by the Division TARC is reserved for the non-routine requests or appeals from the Facility TARC.

The Division TARC is comprised of some of the most senior clinical and non-clinical personnel. Thus, limiting their review to appeals from Facility TARC and non-routine requests for interventions is an efficient use of their abilities and experience. With respect to reviewing requests for surgical interventions as a treatment of gender dysphoria, the clinical personnel on the Division TARC, namely the Medical Director, the Chief of Psychiatry, and the Behavioral Health Director are well positioned to review a patient's medical and mental health

records and objectively assess the totality of a patient's presentation to collectively determine the clinical need for given intervention.

Lastly, with respect to requests for surgical interventions or requests for gender-identity-consistent facility transfers, the final review step required in the Policy acts as a quality control device. The purpose of this final review is to ensure consistency and completeness of the process. This extra attention and dedication of resources is reflective of the Department's commitment to thoroughly and appropriately handling these types of requests.

Finally, the Department has a policy that requires that all of its policies are reviewed annually to allow for swift updates or modifications to the same. This feature is a benefit particularly in areas of healthcare where research is ongoing and best practices and recommendations are evolving. This is indeed the case with respect to healthcare practices related to the transgender and gender diverse patient population. Thus, that the Department is committed to actively monitoring this area for developments and can easily modify the Policy accordingly is an important attribute of the agency's approach to transgender and gender diverse healthcare. Indeed, the Department has already made revisions and updates to the Policy after adopting it.

3. The Review Process Articulated in the Policy Tracks with the Review Process of Other Medical Services.

In general, with respect to reviewing and approving certain medical services, the Department employs a utilization management process. This general policy is articulated in the Department's utilization management policy. The purpose of the Department's utilization management (UM) process is to evaluate the appropriateness of and medical necessity of services to patients. Based on my experience, such a process is routine, necessary, and is typically utilized in correctional healthcare systems, including larger county jails, and all state prison systems, and the federal system, which effectively operate as managed care organizations.

Under the Department's UM policy, a facility-based medical provider (*i.e.*, physician, physician assistant, family nurse practitioner) would submit a request for a medical service. The request would then be reviewed by a UM Physician Review who could defer the request, request additional information, or approve the request. The UM policy also provides for a higher-level review or appeal to the UM Medical Director. The tiered review process set out in the Department's Policy tracks this typical UM process but with a critical and necessary distinction. As explained above, requests for interventions by transgender and gender diverse persons in a correctional setting can implicate medical, behavioral health, and/or non-clinical custody issues such as housing assignments and access to a variety of gender affirming property issues such as hair extension, hair removal, bras, binders, undergarments, make-up, earrings, jewelry, and other personal items and privileges. Thus, in my professional opinion based on my 30 years of direct correctional health care experience, the typical UM process, which only involves medical staff and thus is not interdisciplinary, is insufficient to appropriately and efficiently address the array of such requests. This multidisciplinary review process allows for input from across the Department to ensure that all relevant considerations are made and allows for an efficient and standardized system of reviewing these requests.

Ultimately, the use of a multidisciplinary approach for reviewing requests for interventions by transgender and gender diverse prisoners rather than the typical UM process is a positive aspect of the Policy. The multidisciplinary approach takes into account the uniqueness of gender dysphoria, the variety, uniqueness, and spectrum of transgender individuals, and in particular that the condition presents in various ways and patients seek out various interventions which may implicate many disciplines. In short, a UM process that involves only medical personnel is sufficient for considering most requests for medical services, such as for dentures, eyeglasses, knee

replacement or a pacemaker, but that same process may be insufficient to appropriately consider a request for gender affirming treatment.

The fact that treatments approved by the Division TARC must be reviewed by the Commissioner and Director of Health Services is also helpful to ensure that requests are given full and fair consideration. Notably, certain medical interventions in the UR process similarly require higher level review by the Medical Director or that person's designee. The final review of Division TARC determinations in this evolving area serves to ensure that all appropriate factors are considered. In practice, the final review has never served to overrule any recommendation by the Division TARC to provide an accommodation. Rather, the final review process has been used to send certain recommendations back for additional consideration, where appropriate, and to ensure that all steps have been followed. This benefits the person requesting the accommodation by ensuring that the review is thorough and complete.

In closing, for the reasons stated above, based on my education, training, and experience, the Department's Policy reflects a thoughtful, reasonable, and appropriate approach to addressing the needs of the transgender and gender-diverse incarcerated population.

C. Discussion of Medical Necessity

There is no precise or singular definition of the phrase "medical necessity" as it is interpreted in different ways in various contexts. However, there are formulations and applications of that phrase that are reasonable and some that are not. One such formulation evaluates medical necessity by coupling a patient-specific risk-benefit analysis and an assessment of the efficacy of the proposed intervention as indicated by the scientific literature. This is the approach to medical necessity which the Department applies. On the other hand, Dr. Ettner, a non-physician psychologist who does not work in correctional settings (per available CV, declarations, and expert

report), appears to advance a formulation of “medical necessity” that unreasonably focuses only on the capacity of the intervention to provide some possible therapeutic benefit.

1. A Reasonable Formulation of Medical Necessity

The phrase “medical necessity” can and does mean different things in different contexts and from different perspectives. What a physician determines is medically necessary to adequately treat a particular condition will be guided by that clinician’s education, training, and experience, and will be informed by the patient’s presentation. Inherent in this determination is a patient-specific risk-benefit calculus and an assessment of whether the proposed intervention has been demonstrated, through rigorous medical research or other scientific evidence, to be an effective treatment of the target condition.

2. The Department’s Formulation of Medical Necessity

I have reviewed the position statement (produced at DAC 3404-3415) written by Arthur L. Campbell III, M.D., the Department’s Medical Director. In the position statement, Dr. Campbell articulates his understanding and use of the phrase “medical necessity.” Dr. Campbell writes that “[b]roadly speaking, at the most basic level, a medically necessary procedure is one which is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain.” (DAC 3406) Dr. Campbell notes, however, that the phrase “medical necessity” has varying definitions across various stakeholders (*e.g.*, clinicians, insurers, legislators). (DAC 3406) Moreover, despite these variations, Dr. Campbell describes some core components of medical necessity, namely: (1) a risk-benefit analysis; (2) that the procedure has been determined to be the “standard of care”; and (3) that effective treatment protocols have been developed based on rigorous medical or scientific research. (DAC 3406)

I concur with Dr. Campbell's formulation of medical necessity in the context of reviewing and approving requests for medical services. Dr. Campbell's articulation of medical necessity in the position statement reflects a well-reasoned understanding and application of the phrase. Moreover, it comports with my decades of experience in correctional health care, and in community and academic health care settings.

As discussed above, the Department's Policy, calls for a case-by-case review of requests for consideration of gender-affirming surgery and as such requires a determination of "medical necessity" as articulated in the position statement. This is because a thorough risk-benefit analysis will necessarily require an assessment of the severity of the target condition and potential efficacy of the contemplated intervention, as well as that of alternate treatment options. Additionally, the potential efficacy of an intervention is appropriately informed by the efficacy of the intervention in addressing the targeted condition as demonstrated in the medical literature. Thus, the rigor of the medical and scientific literature is an integral component of a reasonable medical necessity formulation. Lastly, gender affirming surgery, in particular any type of genital surgery, is largely irreversible, and this has significant implications which Dr. Ettner does not address.

3. Dr. Ettner's Formulation of Medical Necessity

Dr. Ettner does not offer a specific definition of "medical necessity." Instead, she makes general statements that simply assume medical necessity or reference statements by organizations like the American Medical Association (AMA) and WPATH. (*See* DE-13-1 ¶¶ 45, 48; Ettner Report ¶ 61). In contrast to Dr. Ettner, I am a physician, a member of the AMA, and I have an understanding of the role, agency, and mission of the AMA. I routinely interface with several correctional medical and psychiatric colleagues who have represented the AMA on the NCCHC

Board of Directors, and several forensic psychiatry colleagues who serve as AMA delegates on behalf of the AAPL.

Both WPATH and Dr. Ettner reference formulations of medical necessity that come from the AMA. *See* Ettner Report ¶¶ 62-63; SOC 8 at 16-17). WPATH specifically refers to and quotes the AMA's definition of "medical necessity" from a 2016 Health Policy, H-320.953, which is attached as Appendix C, and reads, in pertinent part:

Our AMA defines medical necessity as: Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

As the WPATH 8 notes, the phrase "medical necessity" is a term of art that is "common to health care coverage and insurance policies globally." (SOC 8 at S16) Indeed, in the policy cited by WPATH, while the AMA advances a single formulation of "medical necessity," it simultaneously recognizes that various actors in the health industry develop and operate under varying formulations of the phrase, and in particular across a tremendously diverse variety of health care settings which are further complicated by health care staffing, staff and health care facility and equipment and other resource availability, geography (*e.g.*, major metropolitan versus rural, physician and health care staff shortage areas, and locations.) (Appx. C at 1) Moreover, this policy must be considered in its appropriate context. This particular policy, H-320.953, is one of 56 Health Policies published by the AMA and maintained in the "Medical Review" category.³ The vast majority, if not all of the 56 policies, including the one cited by WPATH, in some fundamental

³ https://policysearch.ama-assn.org/policyfinder/search/*/relevant/1/PolicyTopic:%22Medical%20Review%22

way concern physician reimbursement issues. That context must be considered when reviewing the AMA policy.

Similarly, Dr. Ettner references and quotes AMA Resolution 122 (A-08), which reads: “Health experts in GID (this outdated term, “gender identity disorder,” is no longer used), including WPATH, have rejected the myth that these treatments are ‘cosmetic’ or ‘experimental’ and have recognized that these treatments can provide safe and effective treatment for a serious health condition.” (Appendix D at 1) Just as with the Health Policy discussed above, the context of that Resolution is important. The subject of the resolution is titled “Removing Financial Barriers to Care for Transgender Patients.” Thus, the express intention of this resolution is to articulate a basis for obtaining insurance coverage or reimbursement for certain types of care, again within community settings. These coverage and reimbursement issues are not applicable within jails and prisons and other correctional settings.

In short, the AMA’s statements regarding medical necessity referenced by WPATH and Dr. Ettner are less about the practice of medicine and more about the administration and operation of the business of medicine in non-carceral community settings. As indicated in the AMA’s background and mission⁴ the organization is making major and admirable strides for improved access to care, removing insurance and reimbursement barriers that interfere with access to and continuity of care, and insurance reimbursement of all Americans regardless of their socioeconomic status. However, these references to AMA policies and resolutions do not dictate whether a particular procedure is medically necessary for a particular patient in a given situation, particularly an incarcerated patient with no insurance coverage.

⁴ <https://www.ama-assn.org/about>

WPATH 8's references to medical necessity in Chapter 11 similarly do not add anything to the attempt to define this concept. Much of the discussion in Chapter 11 simply assumes "medical necessity" without any articulation of how that phrase is understood or applied. *See e.g.*, (SOC 8 at 104 ("TGD residents in carceral facilities report the lack of access to medically necessary transgender-specific health care"; "People should have access to these medically necessary treatments irrespective of their housing situation within an institution"); (SOC 8 at 106 ("TGD people with gender dysphoria should have an appropriate treatment plan to provide medically necessary surgical treatments that contain similar elements provided to persons who reside outside institutions"); (SOC 8 at 107) ("The denial of medically necessary evaluations for and the provision of gender-affirming surgical treatments and necessary aftercare is inappropriate and inconsistent with these Standards of Care.")).

These sweeping statements simply assume that the care in question is "medically necessary." There is no articulation of what circumstances make the intervention "medically necessary," or what factors are appropriately considered in making that determination. These statements fail to recognize the role and function of qualified correctional medical or mental health professionals. Moreover, the statements appear to be overly dismissive of the essential need for an individual evaluation of each patient and an opportunity to carefully discuss and weigh the risks, benefits, and alternatives and the patient's ability to give informed consent for a recommended treatment intervention. Thus, these statements are of extremely limited value in determining whether a given intervention is "medically necessary."

Dr. Ettner notes that various organizations (e.g., WPATH, the AMA, and others) all support surgery in accordance with the SOC as "medically necessary" treatment for individuals with

“severe gender dysphoria.”⁵ (Ettner Report ¶ 51). Neither the most current American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (DSM-5) nor the DSM-5 TR (Text Revision) nor the current International Classification of Diseases (ICD-10) contain any language regarding “severe” or other levels of grading severity of gender dysphoria (*e.g.*, mild, moderate, severe, etc.). Thus, “severe gender dysphoria” is not the correct use or application of a currently accepted and accurate diagnostic nomenclature. Dr. Ettner also references policy statements and studies which support the “efficacy, benefit, and medical necessity” of treatments, including surgery. (*See* Ettner Report ¶¶ 51-61). Dr. Ettner concludes this section of her report by opining that “Given the extensive experience and research supporting the effectiveness of gender-affirming surgery spanning decades, it is clear that such surgery is a medically necessary, not experimental, treatment for severe gender dysphoria as demonstrated by, among other things, its inclusion as a medically necessary treatment in the SOC.” (Ettner Report ¶ 61). A close review of the bases for Dr. Ettner’s sweeping opinion on this point reveals precisely why her formulation of “medical necessity” (and by extension that of WPATH) cannot be summarily applied in the correctional context.

In paragraph 52, Dr. Ettner notes that research⁶ indicates the “efficacy” and “benefit” of treatments. In paragraphs 53-60, Dr. Ettner refers to studies in support of her conclusion that

⁵ Dr. Ettner does not define “severe” gender dysphoria, nor does she articulate clinical indications of what constitutes severe dysphoria. There is no uniform presentation of gender dysphoria. The symptoms of patients with gender dysphoria can vary widely, as do the degree to which these symptoms can impact their daily lives.

⁶ The studies referenced by Dr. Ettner are low-quality studies subject to many limitations. Indeed, there is a lack of high-quality long-term research demonstrating the efficacy of gender-affirming surgery in treating gender dysphoria in US community settings. Even more concerning, there is no published literature demonstrating the efficacy of gender-affirming surgery in treating gender dysphoria in incarcerated individuals. The current research cited in WPATH SOC and proffered by Dr. Ettner is referenced below and more fully as addressed in the expert report of Fan Li, Ph.D.

gender-affirming surgeries are effective, therapeutic, and in some cases virtually eliminate dysphoria. Indeed, Dr. Ettner asserts that the requested surgery in this case would be curative. (DE-13-1 ¶ 92) In paragraph 56, Dr. Ettner refers to a meta-analysis by researchers at Cornell University, in which, among other conclusions, they state that “gender transition” improves well-being, quality of life, relationship satisfaction, self-esteem and confidence, as well as reducing anxiety, depression, suicidality, and substance use.

In paragraph 58, Dr. Ettner cites studies which she claims have “shown that by alleviating the suffering and dysfunction caused by *severe* gender dysphoria, gender-affirming surgery improves virtually every facet of a patient’s life. This includes satisfaction with interpersonal relationships and improved social functioning, improvement in self-image and satisfaction with body and physical appearance, and greater acceptance and integration into the family.” (Ettner Report ¶ 58) (emphasis added) Additionally, in paragraph 59, Dr. Ettner cites other studies which “have also shown that gender-affirming surgery improves patients’ abilities to initiate and maintain intimate relationships.” These improvements and benefits are in keeping with WPATH’s overall goal of helping “people in accessing safe and effective pathways to achieving lasting personal comfort with their gendered selves with the aim of optimizing their overall physical health, psychological well-being, and self-fulfillment.” (WPATH 8 at S5)

There are undoubtedly certain interventions that may improve people’s lives to some degree. However, fully optimizing one’s physical health, improving social functioning, and relationships, while laudable goals, cannot set the standard for medical necessity in any system with limited resources, including the correctional setting. This is because there are undoubtedly numerous interventions, related to gender dysphoria or other conditions, which may have the possibility of providing some benefit to the patient. But reasonable analyses of these possible

interventions also must take into account their potential benefits weighed against their potential risks, the evidentiary support underlying them, and the possibility that alternative treatments may be available and/or preferable. Otherwise, the term “medical necessity” is reduced to something more akin to “medically beneficial” and all types of possible treatments must always be pursued. In short, the possible capacity of an intervention to more fully optimize one’s physical health, improve social functioning, and improve their relationships, simply cannot form the basis of a “medical necessity” determination. Such a standard would be wholly unworkable.

Under the formulation of the phrase “medically necessary” as used by Dr. Ettner and WPATH, an intervention which may provide some benefit vis-à-vis a patient’s gender dysphoria becomes medically necessary. The implication of such a formulation goes beyond interventions to treat gender dysphoria. The same logic would make a host of other interventions “medically necessary” to treat other conditions. For example, a patient with a perception of a large or crooked nose, small breasts, skin wrinkles, droopy eyelids, acne scars/scarring, a large mole, or facial sagging or other distress or discomfort due to perceived facial or body features may derive a benefit from procedures targeting that body feature, such as a rhinoplasty, breast augmentation, botox injections, blepharoplasty (surgical rejuvenating procedure on the upper or lower eyelids), dermabrasion, or facelifts. Similarly, someone who experiences distress or discomfort from a mole, skin tag, birthmark, scar or tattoo, may derive a benefit from a dermatological procedure such as mole, skin tag, birthmark, scar, or tattoo removal utilizing laser treatments or the latest surgical technology or procedure. Under Dr. Ettner’s logic these procedures would be “medically necessary” because they may well benefit the patient by alleviating, to some degree, their perceived distress from their physical appearance or characteristics or otherwise improving their lives.

As a further example, many incarcerated persons experience depressed or dysphoric (unhappy) mood due to being incarcerated and a variety of stressors such as living apart from family/loved ones, a perception of a lack of out of cell time, prolonged delays in postconviction appeals, prospect for parole, conflict with cellmates, other inmates, custody staff, and lack of contact or visitation, etc. Also, there are a variety of other potential correctional stressors or issues regarding custody-based rules, privileges, custody level, work assignments, educational and recreational opportunities, and past or pending disciplinary infractions. Additionally, there may be a variety of anxiety symptoms, insomnia, and other DSM-5-TR recognized mental disorders or adjustment disorders. If research indicates⁷ that certain types of massages may provide a benefit to patients with such conditions by improving their mood, reducing anxiety, alleviating stress, or improving sleep, then under the formulation of “medical necessity” advanced by the Dr. Ettner, those massages become medically necessary for those patients. Indeed, Dr. Ettner agrees that massage therapy could be considered *medically necessary*. See DE-22-1 ¶ 43.

Under that sort of formulation, correctional systems would be required to approve and provide all manner of accommodations, treatments, and care, simply because they may improve a person’s general well-being or self-esteem. Moreover, under this sort of formulation, there would be no reasonable basis for a correctional institution to deny requests for interventions beyond those related to gender dysphoria. For example, if as Dr. Ettner appears to agree, that massage therapy could be medically necessary for those with anxiety, depression, or sleep disorders, then so too would be liposuction for a person with clinical depression related to their obesity, perceived fat

⁷ See, Barreto DM, Batista MVA. Swedish Massage: A Systematic Review of its Physical and Psychological Benefits. Adv Mind Body Med. 2017 Spring;31(2):16-20. PMID: 28659510, which is a meta-analysis that suggests that Swedish massage creates a sense of well-being and joy, reduces anxiety and stress and can improve sleep.

distribution in their abdomen, hips, thighs, buttocks, or any other possible body image preoccupation or concern. For those reasons, Dr. Ettner's formulation of "medical necessity" is flawed and cannot be appropriately reasonably applied in a correctional system.

Overall, in my professional opinion, the definition of medically necessary applied by the Department is far superior in that it is workable and appropriately accounts for factors that should be considered as part of these determinations – including an individualized risk/benefit/alternatives assessment and an assessment of the medical effectiveness of the requested intervention. The Department's definition is consistent with how these determinations are made, and must be made, in the real world.

D. Evaluation of Mrs. Zayre-Brown's Request

In this section of my report, I will discuss the Department's decision with regard to Plaintiff's request for a vulvoplasty as a treatment for gender dysphoria. This will include an evaluation of whether there were any clinical indications that the surgery was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain. Additionally, in this section I will discuss the state of the scientific and medical research regarding the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria.

As explained above, the phrase "medical necessity" is subject to varying formulations. A reasonable and appropriate formulation of the phrase can include a patient-specific risk-benefit and alternatives analysis and a determination of whether the contemplated intervention has been shown, through rigorous high-quality research, to be effective at treating the target condition. As explained below, in this case, there was a lack of any clinical indication that without the vulvoplasty Plaintiff was at serious risk of some severe distress, harm, or disability. Additionally, there is a lack of high-quality research regarding the efficacy of such an intervention. Therefore,

it is my opinion, based on my education, training, and experience that the individualized review and analysis of her medical and mental health and other psychosocial history by the Department to not approve the requested vulvoplasty as a treatment for gender dysphoria was a reasonable and appropriate decision.

1. The Risk-Benefit Analysis in Plaintiff's Case

The risk-benefit analysis is informed by a determination of the harm a patient is or is likely to experience absent the intervention and how that is balanced against the potential benefit to the patient in proceeding with the intervention. In conducting that assessment, the Division TARC considered a comprehensive review of Plaintiff's medical and behavioral health history (DAC 3400, 3417) and did not identify any clinical indications that Plaintiff was suffering from any severe distress, harm, or disability. This is critically important in a risk-benefit analysis as the lack of some severe distress, harm, or disability absent the contemplated intervention indicates a lack of risks of not approving the surgery.

I reached this same conclusion in my review—that there was little to no clinical indications that Plaintiff was or would be at risk of some severe distress, harm, or disability absent the requested vulvoplasty. Thus, the Defendants' determination that surgery was not medically necessary was reasonable under the circumstances. These conclusions were informed by a review of Plaintiff's medical records, a review of her deposition testimony, and my review of the in-person psychological evaluation of her conducted by Dr. Boyd.

a. Plaintiff's Medical Records Do Not Demonstrate Clinically Significant Mental or Emotional Distress

The hallmark of gender dysphoria is clinically significant distress or impairment in social, occupational, or other important areas of functioning. In the correctional setting such distress or impairment can manifest itself in many ways. For instance, patients can wrestle with negative self-

image, poor body image, and signs and symptoms of other DSM-5 mental disorders such as depression, anxiety, PTSD, and other psychosocial distress. Clinical indicators of these conditions might include lack of appetite, impaired sleep, lack of energy, decreased interest in usual pleasurable activities, under or over-eating when distressed, guilt or preoccupations, decreased concentration, and weight loss due to depressive or anxiety symptoms, and suicidal ideation, intent or plan. In addition to these symptoms, patients with gender dysphoria may experience impairment in the activities of daily living. This impairment is often indicated by an inability to perform activities of daily living, such as not being able to obtain or maintain employment within the prison setting, impaired social and familial relationships. Importantly, these indicators can appear differently across patients and occur on a spectrum of severity.

Based on my review of Plaintiff's medical records, including her mental health visits, routine check-ups, sick calls, endocrinology appointments, and other medical records, the typical indicators of significant mental distress or impairment of the activities of daily living are not present. While Plaintiff's chart does indicate that she struggled to adjust to life in a men's prison, she appears to have adjusted well to life within the female unit of Anson Correctional Institution, which she was assigned from 2019 until May of this year (when she was moved to a minimum custody facility). Indeed, after an initial adjustment period, she testified that she had been doing fairly well at Anson, at least in the last two years leading up to her deposition—she rated her level of anxiety 5 out of 100. (Zayre-Brown Dep. 142:10-143:18) Additionally, she reports being close with her family members. (Zayre-Brown Dep. 15:6-12) She's also been productive while incarcerated, working in the commissary, and completing educational programming. (Zayre-Brown Dep. 27: 20 - 28:1, 165:24) In short, her records indicate that she has not experienced and

is not experiencing an impairment in her current activities of daily living that can be considered clinically significant.

Similarly, Plaintiff's medical records do not indicate that she has or is currently experiencing significant emotional or mental distress. Over the years she has routinely described herself as a happy person and denied experiencing depression or anxiety. Plaintiff has also consistently denied suicidal ideation. With regard to suicidality, Plaintiff has described an event on March 2, 2019, which she refers to as a suicide attempt. However, the medical records associated with that event call into question Plaintiff's accounting of it as a suicide attempt. For instance, there is no mention in any of the medical records both from the prison or the outside emergency department that Plaintiff mentioned ingesting a large number of pills, nor that any clinician suspected anything of the sort.

Additionally, there is one instance of a reported self-harm attempt in her medical records. In this incident, Plaintiff reported that she placed a band around her penis. However, this episode appears to be isolated, was self-reported, and most importantly was described contemporaneously by Plaintiff as a protest out of frustration with a perceived delay in the process of setting up a surgical consult, as opposed to an actual attempt at self-harm. Notably, the records indicate that she voluntarily removed the band without any injury or medical attention required. Also, there is no indication in any of her records that she required a nursing assessment or emergency medical evaluation, offsite transfer to an emergency department or hospital, a urology consultation or other intervention. Most importantly, there is no evidence of any other genital harm, injury, or attempted or completed auto-castration or attempted or completed auto-penectomy.

Lastly, there was an episode in December 2020, when Plaintiff reported having thoughts of self-harm. Importantly, however, within 24 hours of first reporting these thoughts and being

transferred to an inpatient mental unit⁸, Plaintiff denied any suicidal ideation or thoughts of self-harm. Indeed, she would continue to deny any suicidal ideation or thoughts of self-harm for approximately the next month. Only upon being informed that she would be leaving the inpatient unit and returning to her assigned facility, did Plaintiff begin to threaten self-harm. Notably, after being returned to her assigned facility, there is no record of Plaintiff engaging any self-harm or expressing thoughts of the same.

In short, Plaintiff's medical records demonstrate that whatever distress she may have as a result of her gender dysphoria, it was and is well managed, not severe, and not causing any impairments to her daily living activities. The lack of such clinical indications of distress in a patient's medical chart is an important consideration when determining whether a given intervention is medical necessary. This is because if there is reason to believe that the intervention is necessary to prevent, and will be effective at ameliorating, such severe distress, harm, or disability, then the intervention might be said to be medically necessary. However, in Plaintiff's case there was and is no clinically significant indication that she was or is suffering from severe distress, harm, or disability as a result of her gender dysphoria. Thus, the Division TARC's recommendation to not approve the surgery as not medically necessary was reasonable based on the absence of any indication that without the surgery she was at risk of death, significant disability, or suffering from severe pain.

4. The Medical Literature is Inconclusive

The state of the scientific and medical literature regarding the efficacy of a particular intervention in treating a specific condition can be a critical component of determining medical

⁸ The inpatient mental health unit was located at North Carolina Correctional Institution for Women, a facility that Plaintiff had repeatedly been requesting to be transferred.

necessity. To that end, it is my opinion, based on my education, training, and experience, that there is a lack of high-quality scientific and medical literature indicating the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria. Also, there is no literature within incarcerated patient populations.

The Division TARC evaluated the state of the scientific and medical literature and in particular the lack of high-quality scientific and medical literature regarding the long-term efficacy of gender-affirming surgery as a treatment for gender dysphoria in reaching its decision. (*See* DAC 3400-3403, 3417-3418). I am generally familiar with the research referenced by the Division TARC, and that which is cited by WPATH and Dr. Ettner regarding the long-term efficacy of gender-affirming surgery in treating gender dysphoria. It is my understanding that this body of research is lacking in robust high-quality studies. Moreover, the studies that do exist are of low quality and suffer from many basic design problems, such as: small sample sizes, lack of baseline psychological testing to identify baseline and pre-existing mental disorders and personality disorders in particular, lack of baseline and outcome measures, lack of validated measures, lack of a control group, lack of multiple sizes, lack of standardization for controlling outside variables (various relational and psychosocial stressors, substance use, and other conflicts unrelated to the surgery), sample bias, and more. Much of the literature is based on questionnaires re: perceived efficacy and satisfaction and the like which are not scientifically valid.

In addition, I have reviewed the expert report prepared and submitted in this case by Fan Li, Ph.D. In that report, Dr. Li reviews over 80 separate studies that were cited by Dr. Ettner and/or WPATH in support of various assertions. Dr. Li concludes that in her opinion, as an expert who specializes in statistical methodology for comparative effectiveness research, that the body of

studies that she reviewed do not provide rigorous and consistent statistical evidence of the benefits in quality of life and well-being of gender-affirming treatments.

As I stated above, the efficacy of the proposed intervention, as demonstrated through rigorous medical and scientific research, is an integral component of determining medical necessity. As Dr. Li's comprehensive report demonstrates, and as the literature review of Dr. Campbell (*see* DAC 3412) and that of my own (*see* DE-18-8 ¶¶ 53-60) indicates, there is a lack of high-quality research on the topic of the long-term efficacy of gender-affirming surgery in treating gender dysphoria. As such, in my professional opinion, the lack of such research is an appropriate consideration when determining whether gender-affirming treatment is medically necessary.

b. Conclusions Regarding the Department's Decision to Not Approve Plaintiff's Request for a Vulvoplasty

With regard to the Department's decision to not approve the Plaintiff's requested vulvoplasty as treatment for gender dysphoria as not medically necessary, the Department's policy provides for an individualized assessment of each request, and such an individualized assessment occurred in this case. There was no clinical indication that the surgery was required to protect life, to prevent clinically significant illness or significant disability, or to alleviate clinically significant severe pain. There is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria. Therefore, based on the foregoing and upon my education, training, and experience, I conclude that the Department's decision to not approve the requested vulvoplasty as a treatment for gender dysphoria was a well-reasoned and thus a reasonable and appropriate decision.

III. Conclusion

In closing, in this report I offer the following primary conclusions and opinions:

(1) The EMTO policy comports with or exceeds what I would consider to be an acceptable standard for a comprehensive set of correctional health care protocols for the evaluation and management of transgender health care.

(2) Regarding medical necessity,

- a. the Department applied a reasonable definition of “medical necessity” that involved a patient-specific risk-benefit analysis coupled with a determination of the status of the scientific literature indicating that the proposed intervention is effective at treating the target condition; and
- b. by contrast, the definition advanced by Dr. Ettner focuses solely on a possible therapeutic benefit to be had by the intervention and is unworkable in the correctional context (and otherwise).

(3) Regarding the Division TARC’s decision to deny the request for gender affirming surgery, the denial was appropriate and reasonable, because:

- a. there was no clinical indication that the surgery was necessary to protect life, to prevent clinically significant illness or significant disability, or to alleviate severe pain; and
- b. there is a lack of high-quality scientific research indicating the long-term efficacy of gender-affirming surgery as an effective treatment for gender dysphoria.

The statements, conclusions, and opinions stated herein are based upon my education, training, and three decades of clinical and administrative experience in correctional health care,

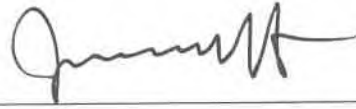
which includes direct patient care and overall clinical and administrative responsibility for the provision of gender dysphoria evaluation and treatment within the TDCJ system for the last fifteen years, as well as my review of the various sources of the information as described herein. All of my conclusions and opinions are stated to a reasonable degree of medical, psychiatric, and mental health certainty. Additionally, I reserve the right to revisit and revise the conclusions and opinions stated herein based on newly acquired information or other evidence which may be presented to me at some later date.

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SIGNATURE PAGE TO FOLLOW

I, Joseph V. Penn, MD, pursuant to 28 U.S.C. § 1746, declare that the foregoing is true and correct.

This the 5th, day of July, 2023.



Joseph V. Penn, MD, CCHP FAPA

APPENDIX A – EXPERT REPORT OF JOSEPH O. PENN, M.D.

List of Materials Relied Upon in Drafting This Report

1. Plaintiff's complaint (DE-1)
2. Defendants' Motion to Dismiss and related briefs. (DE-9, 10, 17, and 21)
3. Plaintiff's motion for a preliminary injunction and related briefs, including the first and second declarations of Randi C. Ettner, Ph.D. (DE-13, 14, 18, and 22)
4. The Court's order denying Defendants' motion to dismiss and denying Plaintiff's motion for a preliminary injunction. (DE-25)
5. Defendants' Answer (DE-26)
6. The expert report of Randi C. Ettner, Ph.D., dated February 3, 2023, including all appendices.
7. The document titled, *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, published in the International Journal of Transgender Health.
8. The document titled, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7, published by the World Professional Association for Transgender Health.
9. Mrs. Zayre-Brown health and related records (DAC 0001-3368, 3381-3403, 3416-3418)
10. The Department's policy titled *Evaluation and Management of Transgender Offenders* (DAC 3421-3430)
11. The Department's policy titled *Utilization Management*¹

¹ This policy is publicly available at <https://public.powerdms.com/NCDAC/tree/documents/2050350>.

12. The March 23, 2022, Position Statement, written by Arthur L. Campbell, III, M.D.
(DAC 3404-3415)
13. The video and transcript of the deposition of Mrs. Zayre-Brown.
14. The transcript of the Department's 30(b)(6) deposition (both parts).
15. The transcript of the deposition of Lewis Jon Peiper, Ph.D.
16. The transcript of the deposition of Arthur L. Campbell, III, M.D.
17. The transcript of the deposition of Brian Sheitman, M.D.
18. The transcript of the deposition of Gary Junker, Ph.D.
19. The transcript of the deposition of Patricia Hahn, Ph.D.
20. The transcript of the deposition of Brandeshawn Harris.
21. Expert report of Fan Li, Ph.D., dated June 17, 2023.
22. The recording of the in-person assessment of Mrs. Zayre-Brown conduct on June 20, 2023, by Sara E. Boyd, Ph.D.
23. The expert report of Sara E. Boyd, Ph.D., dated July 5, 2023.

APPENDIX B – EXPERT REPORT OF JOSEPH O. PENN, M.D.

List of Expert Testimony – Rule 26(a)(2)(B)(v)

2023

1. Carrie Roth-Walker, individually, and on behalf of the statutory beneficiaries of Branden Roth, deceased v. Christopher Nanos, Sheriff of Pima County; Pima County, Wellpath, et al; Jail Inmate on Jail Inmate Assault Resulting in Death

2022

1. John Rapp, in his Personal Capacity and as Personal Representative of the Estate of Nicholas Rapp v. NaphCare, Inc., Kitsap County, et al.; Jail Suicide

2. Mariah M. Walters, as Personal Representative of the Estate of Elizabeth Najar v. Board of County Commissioners of Chaves County, New Mexico and CorrHealth, LLC d/b/a CorrHealth LLC, Jail Suicide

3. G.H., et al., v. Eric S. Hall, Florida Department of Juvenile Justice and Secretary of the Department of Juvenile Justice, et al., United States District Court, Northern District of Florida, Risk of Mental Harm to Detained Juveniles Housed in Behavioral Confinement While in State of Florida Juvenile Detention Centers

4. G.H., et al., v. Eric S. Hall, Florida Department of Juvenile Justice and Secretary of the Department of Juvenile Justice, et al., United States District Court, Northern District of Florida, Risk of Mental Harm to Detained Juveniles Housed in Behavioral Confinement While in State of Florida Juvenile Detention Centers

5. Wilhen Hill Barrientos, et al. v. CoreCivic, Inc. United States District Court, Middle District of Georgia, Mental Risk of Harm to U.S. Immigration and Customs Enforcement

(ICE) Detainees Confined, with a Focus on ICE Detainees' Participation, Housing Assignments, and Privileges (or Loss Thereof) While Housed at the Stewart Detention Center, Lumpkin, Georgia
2021

1. Victor Parsons; et al., on behalf of themselves and all others similarly situated, and Arizona Center for Disability Law v. David Shinn, Director, Arizona Department of Corrections Rehabilitation and Reentry; and Larry Gann, Assistant Director, Medical Services Contract, Monitoring Bureau, Arizona Department of Corrections Rehabilitation and Reentry, in their official capacities: U.S. District Court, District of Arizona, Phoenix, Arizona. Arizona Department of Corrections State Prisoners: Unconstitutional Conditions of Confinement, Access to and Provision of Clinically Appropriate and Individually Determined Mental Health Evaluation and Treatment Services, Mental Health Intake Health Screening and Procedures, Mental Health and Psychiatric Evaluation and Treatment Services, Other Mental Health Policies and Procedures, Mental Health and Psychiatric Staffing, Suicide Prevention Policy and Procedures, Audits and Compliance Reports, Access to Mental Health and Psychiatric Care

2. Stephen Knox v. Rob Jeffreys, Dr. Kelly Renzi, Dr. Andrew Tilden and Wexford Health Sources, Inc., et al, United States District Court, Central District of Illinois, Mental Health Conditions and Treatments of Mr. Stephen Knox While Housed in Restrictive Housing

3. Bryan P. Bonham v. State of Nevada, Nevada Department of Corrections, et al, United States District Court, District of Nevada, Is Restriction of a State Prison Inmate's Out of Cell Activities Due to COVID Precautions Reasonable or Does This Pose Risk Of Mental Harm or Mental Disorder(s)

2020

1. William A. Ruda, MD and Sandra L. Ruda v. State of New Jersey Department of Human Services; Ann Klein Forensic Center; State of New Jersey Department of Corrections; Moises Polanco; Carrier Clinic, Inc. et al. Superior Court of New Jersey, Somerset County, Forensic Patient on Physician Assault Resulting in Injuries

2. Debra P. Vought and Eric Vought as the Permanent Guardians Acting on Behalf of Jared R. West v. San Juan County Regional Medical Center, Inc., Presbyterian Medical Services, Inc., et al; Aztec District Court, Aztec, New Mexico, Jail Mental Health Services Medical Malpractice Screening Panel Testimony (confidential by state statute) – I am unable to reference the name, issue, city, or state as it would identify the case

2019

1. State of Texas v. Pontrey Jones, Judicial District Court 403rd District Court, Travis County, Austin, Texas, General Practices and Procedures for Providing Mental Health Services to Texas Department of Criminal Justice (TDCJ) Offenders

2. Luis Alberto Mendez v. County of Sacramento; The Regents of the University of California; Gregory Sokolov, MD; Danielle Dass, LCSW; Charlene Williams, NP; Andrea Javist; Deputy Sheriff Tineley Sietz; Deputy Sheriff Alexander Egenberger; Deputy Sheriff Jordan Lee, United States District Court for the Eastern District of California Sacramento Division, Sacramento California, Jail Self Harm.

3. Connie McMillin, as Independent Executrix of the Estate of Lee B. Albin, Deceased, and Heather Albin and Claire McMillin-Albin v. Oceans Behavioral Hospital Lufkin; Oceans Behavioral Hospital of Lufkin, LLC; Oceans Healthcare, LLC; Vernon Johnson, MD; and Vernon Charles Johnson, MD, PA, Angelina County, Texas.

Medical Review

Definitions of "Screening" and "Medical Necessity" H-320.953

Topic: Medical Review	Policy Subtopic: NA
Meeting Type: Annual	Year Last Modified: 2016
Action: Reaffirmed	Type: Health Policies
Council & Committees: Council on Medical Service	undefined

(1) Our AMA defines screening as: Health care services or products provided to an individual without apparent signs or symptoms of an illness, injury or disease for the purpose of identifying or excluding an undiagnosed illness, disease, or condition.

(2) Our AMA recognizes that federal law (EMTALA) includes the distinct use of the word screening in the term "medical screening examination"; "The process required to reach, with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist."

(3) Our AMA defines medical necessity as: Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

(4) Our AMA incorporates its definition of "medical necessity" in relevant AMA advocacy documents, including its "Model Managed Care Services Agreement." Usage of the term "medical necessity" must be consistent between the medical profession and the insurance industry. Carrier denials for non-covered services should state so explicitly and not confound this with a determination of lack of "medical necessity".

(5) Our AMA encourages physicians to carefully review their health plan medical services agreements to ensure that they do not contain definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.

(6) Our AMA urges private sector health care accreditation organizations to develop and incorporate standards that prohibit the use of definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.

(7) Our AMA advocates that determinations of medical necessity shall be based only on information that is available at the time that health care products or services are provided.

(8) Our AMA continues to advocate its policies on medical necessity determinations to government agencies, managed care organizations, third party payers, and private sector health care accreditation organizations.

Policy Timeline

CMS Rep. 13, I-98 Reaffirmed: BOT Action in response to referred for decision Res. 724, A-99 Modified: Res. 703, A-03 Reaffirmation I-06 Reaffirmed: CMS Rep. 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 122
(A-08)

Introduced by: Resident and Fellow Section, Massachusetts Medical Society, California Medical Association, Medical Society of the State of New York

Subject: Removing Financial Barriers to Care for Transgender Patients

Referred to: Reference Committee A

Whereas, The American Medical Association opposes discrimination on the basis of gender identity¹ and

Whereas, Gender Identity Disorder (GID) is a serious medical condition recognized as such in both the Diagnostic and Statistical Manual of Mental Disorders (4th Ed., Text Revision) (DSM-IV-TR) and the International Classification of Diseases (10th Revision),² and is characterized in the DSM-IV-TR as a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering;³ and

Whereas, GID, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death;⁴ and

Whereas, The World Professional Association For Transgender Health, Inc. ("WPATH") is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders,⁵ and has established internationally accepted Standards of Care⁶ for providing medical treatment for people with GID, including mental health care, hormone therapy and sex reassignment surgery, which are designed to promote the health and welfare of persons with GID and are recognized within the medical community to be the standard of care for treating people with GID; and

Whereas, An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID;⁷ and

Whereas, Health experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition;⁷ and

Whereas, Physicians treating persons with GID must be able to provide the correct treatment necessary for a patient in order to achieve genuine and lasting comfort with his or her gender, based on the person's individual needs and medical history;⁸ and

Whereas, The AMA opposes limitations placed on patient care by third-party payers when such care is based upon sound scientific evidence and sound medical opinion;^{9, 10} and

Whereas, Many health insurance plans categorically exclude coverage of mental health, medical, and surgical treatments for GID, even though many of these same treatments, such as psychotherapy, hormone therapy, breast augmentation and removal, hysterectomy, oophorectomy, orchiectomy, and salpingectomy, are often covered for other medical conditions; and

Whereas, The denial of these otherwise covered benefits for patients suffering from GID represents discrimination based solely on a patient's gender identity; and

Whereas, Delaying treatment for GID can cause and/or aggravate additional serious and expensive health problems, such as stress-related physical illnesses, depression, and substance abuse problems, which further endanger patients' health and strain the health care system; therefore be it

RESOLVED, That the AMA support public and private health insurance coverage for treatment of gender identity disorder (Directive to Take Action); and be it further

RESOLVED, That the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician (Directive to Take Action).

Fiscal Note: No significant fiscal impact.

References

1. AMA Policy H-65.983, H-65.992, and H-180.980
2. Diagnostic and Statistical Manual of Mental Disorders (4th ed.. Text revision) (2000) ("DSM-IV-TR"), 576-82, American Psychiatric Association; International Classification of Diseases (10th Revision) ("ICD-10"), F64, World Health Organization. The ICD further defines transsexualism as "[a] desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex." ICD-10, F64.0.
3. DSM-IV-TR, 575-79
4. Id. at 578-79.
5. World Professional Association for Transgender Health: <http://www.wpath.org>. Formerly known as The Harry Benjamin International Gender Dysphoria Association.
6. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, Sixth Version (February, 2001). Available at <http://wpath.org/Documents2/socv6.pdf>.
7. Brown G R: A review of clinical approaches to gender dysphoria. J Clin Psychiatry. 51(2):57-64, 1990. Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 15(9):1447-57, 2006. Best L, and Stein K. (1998) "Surgical gender reassignment for male to female transsexual people." Wessex Institute DEC report 88; Blanchard R, et al. "Gender dysphoria, gender reorientation, and the clinical management of transsexualism." J Consulting and Clinical Psychology. 53(3):295-304. 1985; Cole C, et al. "Treatment of gender

dysphoria (transsexualism).” Texas Medicine. 90(5):68-72. 1994; Gordon E. “Transsexual healing: Medicaid funding of sex reassignment surgery.” Archives of Sexual Behavior. 20(1):61-74. 1991; Hunt D, and Hampton J. “Follow-up of 17 biologic male transsexuals after sex-reassignment surgery.” Am J Psychiatry. 137(4):432-428. 1980; Kockett G, and Fahrner E. “Transsexuals who have not undergone surgery: A follow-up study.” Arch of Sexual Behav. 16(6):511-522. 1987; Pfafflin F and Junge A. “Sex Reassignment. Thirty Years of International Follow-Up Studies after Sex Reassignment Surgery: A Comprehensive Review, 1961-1991.” IJT Electronic Books, available at <http://www.symposium.com/ijt/pfaefflin/1000.htm>; Selvaggi G, et al. “Gender Identity Disorder: General Overview and Surgical Treatment for Vaginoplasty in Male-to-Female Transsexuals.” Plast Reconstr Surg. 2005 Nov;116(6):135e-145e; Smith Y, et al. “Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals.” Psychol Med. 2005 Jan; 35(1):89-99; Tangpricha V, et al. “Endocrinologic treatment of gender identity disorders.” Endocr Pract. 9(1):12-21. 2003; Tsoi W. “Follow-up study of transsexuals after sex reassignment surgery.” Singapore Med J. 34:515-517. 1993; van Kesteren P, et al. “Mortality and morbidity in transsexual subjects treated with cross-sex hormones.” Clin Endocrinol (Oxf). 1997 Sep;47(3):337-42; World Professionals Association for Transgender Health Standards of Care for the Treatment of Gender Identity Disorders v.6 (2001).

8. The Harry Benjamin International Gender Dysphoria Association’s Standards of Care for Gender Identity Disorders, at 18.
9. Id.
10. AMA Policy H-120.988

Relevant AMA policy

H-65.983 Nondiscrimination Policy

The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur. (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05)

H-65.992 Continued Support of Human Rights and Freedom

Our AMA continues (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies. (Sub. Res. 107, A-85; Modified by CLRPD Rep. 2, I-95; Reaffirmation A-00; Reaffirmation A-05)

H-180.980 Sexual Orientation as Health Insurance Criteria

The AMA opposes the denial of health insurance on the basis of sexual orientation. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians

The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon

sound scientific evidence and sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04)